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Paxman Limb Cryocompression System to be used in SWOG Cancer Research Network Study Testing for Prevention of Chemotherapy-Induced Peripheral Neuropathy

Paxman today announces they have been selected by the SWOG Cancer Research Network, an independent global cancer research community that designs and conducts publicly funded clinical trials, for the Paxman Limb Cryocompression System (PLCS) to be used in a prospectively designed study looking at prevention of Chemotherapy-Induced Peripheral Neuropathy (CIPN).

S2205 "*ICE COMPRESS: Randomized Trial of Limb Cryocompression Versus Continuous Compression Versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy"* is a clinical trial conducted by SWOG, sponsored and approved by the National Cancer Institute (NCI).

SWOG, a consortium of academic institutions, hospitals, community hospitals, community-based physician cooperatives, and individual physician offices, is one of five network groups comprising the National Cancer Institute (NCI) National Clinical Trials Network (NCTN) and as such conducts adult cancer clinical trials sponsored and approved by the NCI.

The recently published ASCO and ESMO guidelines highlight cryotherapy and compression as promising interventions, but neither is recommended due to lack of efficacy data from rigorous randomized trials. Preliminary evidence suggests that continuous-flow cryotherapy (with or without cyclic compression) and continuous compression therapy, compared to frozen gloves and socks, may be safer, more tolerable, and easier to implement on a large scale. Thus, it is important to rigorously evaluate these modalities in a randomized controlled trial.

Dr. Melissa Accordino of Columbia University Irving Medical Center and Principal Investigator of the study said, "We have made tremendous advances in the diagnosis and treatment of many cancers; thus many patients are fortunately living longer after a cancer diagnosis. However, as people are living longer, there are more opportunities to develop side effects that can greatly impact quality of life, such as chemotherapy induced peripheral neuropathy. We are hoping that results from this study will help to identify a strategy to safely and effectively prevent chemotherapy induced peripheral neuropathy. If this happens, this will lead to remarkable improvement in the lives of many patients with cancer going forward."

In this cooperative group study, participants scheduled to receive taxane-based therapy will be randomly assigned to receive either 1) cryocompression therapy; 2) continuous compression therapy; or 3) low cyclical pressure alone.

Participants will be randomized in a 1:1:1 fashion to cryocompression, continuous compression, or low cyclic compression to all extremities, to be administered for 30 minutes prior to taxane therapy, during taxane therapy, and for 30 minutes after completion of taxane therapy. The study aims to enrol 777 patients.

PLCS devices will be shipped in January to a minimum of 25 locations, with an aim to open the study to enrolment in Q1 2023.

“SWOG clinical trials have changed the standards of cancer care by providing unbiased, well powered clinical studies to validate prescriptive outcomes that inform patient management guidelines”, said Richard Paxman, CEO of Paxman. “The knowledge gained from this large, randomized Phase III study could be practice changing and lead to significant quality of life improvements among cancer survivors. Secondarily, the study will assess the safety, tolerability, and satisfaction with cryocompression therapy and compression therapy. This study will help clinicians determine the most effective and most tolerable strategy to prevent taxane-induced CIPN, we are excited to support patients in addressing this debilitating side-effect.”

About CIPN

Chemotherapy-induced peripheral neuropathy (CIPN) is a severe dose-limiting toxicity of paclitaxel and docetaxel, which are both widely used drugs for the treatment of common cancers including breast, ovarian, endometrial, lung, and gastric cancers. ***([i])*** CIPN is extremely prevalent; rates of Grade 2 or higher sensory neuropathy have been reported at 27% in patients with breast cancer (BC) after 12 cycles of weekly paclitaxel and at 20-21% in patients with endometrial or ovarian cancer who received 6 cycles of 3-weekly paclitaxel and carboplatin. ***([ii], [iii], [iv])*** CIPN has a profound impact on quality of life, often limiting daily functioning and motor activities, and can persist for years after treatment. ***([v], [vi])***

At present, dose modification is the most successful approach to prevent worsening CIPN; however, there is potential for lower chemotherapy efficacy, which could result in poorer survival. In the American Society of Clinical Oncology (ASCO) and European Society for Medical Oncology (ESMO) CIPN guidelines, several non-pharmacologic interventions were listed for the prevention of CIPN. ***([vii], [viii])*** However, none have been proven to be effective in large, randomized trials, and are thus not recommended for use in clinical practice. There has been considerable emerging interest in non-pharmacological approaches such as cryotherapy and compression therapy.

Since 2019, Paxman have been working in partnership with a Singapore research team from National University Cancer Institute, Singapore (NCIS) at the National University Hospital (NUH) and the N.1 Institute for Health at the National University of Singapore (NUS) in developing the PLCS, a portable limb cryocompression device specifically targeting prevention of CIPN in cancer patients.

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About Us

The Paxman Scalp Cooling System has been developed by the Paxman family to reduce hair loss in breast cancer patients undergoing chemotherapy. The concept behind the system came when the mother of four, Sue Paxman, experienced first-hand the trauma of chemotherapy-induced hair loss. With close to 4,400 systems delivered in to hospitals, clinics and treatment centres around the world, PAXMAN is the leading supplier of Scalp Cooling technology. PAXMAN's scalp-cooling cap is made from lightweight, biocompatible silicone that is soft and flexible, providing a snug yet comfortable fit during treatment. PAXMAN AB (publ) has its headquarters in Karlshamn (Sweden), with subsidiaries in Huddersfield (UK) and Houston, Texas (US).

The PAXMAN share is listed on Nasdaq First North Growth Market.
FNCA Sweden AB is the company's Certified Adviser.

Attachments

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